K070400

FEB 2 8 2007

510(k) SUMMARY

The Summary of Safety and Effectiveness on the LiteCure, LLC. LCT-1000 laser reflects data available and represented at the time the submission was prepared, but caution should be exercised in interpreting the data. The results of future studies and or tests may require alterations of the conclusions or recommendations set forth.

Applicant	Brian Pryor LiteCure, LLC 930 Old Harmony Road, Suite A Newark, Delaware 19713
Telephone **Facsimile**	302-709-0408 302-709-0409
Date	December 20, 2006
Name	LC Therapy, Model LCT-1000 Laser
Classification	Infrared Lamp, 21 CFR 890.5500
Predicate:	• K-Laser Therapy Probe – Cleared under K050070 market clearance date May 25, 2005 • ALT Laser, Model VTR 75 – Cleared under K031612 market clearance date December 11, 2003
Description	LC Therapy, Model LCT-1000 Laser is a compact medical laser system. The laser light delivery system consists of a flexible optical fiber threaded through a lightweight wand. Activation occurs when the operator enables the laser and presses the foot switch. Release the foot switch to deactivate the laser. Depending on laser system configuration, the foot switch can function as on/off switch. A touch-screen display panel allows the operator to adjust or set laser output level. The laser can operate in continuous wave mode or controlled pulse mode.
Intended Use	LC Therapy, Model LCT-1000 is indicated for emitting energy in the infrared Spectrum to provide topical heating for the purpose of elevating tissue temperature for temporary relief of minor muscle and joint pain, muscle spasm, pain and stiffness associated with arthritis and promoting relaxation of the muscle tissue and to temporarily increase local blood circulation.
Contraindications	• Do not apply infrared light to abdominal or lumbosacral points in pregnant females. • Do not apply infrared light to the epiphyseal lines in children. • Do not apply infrared light to the thorax or over the pacemaker itself in patients with pacemakers. • Do not apply infrared light over the thyroid gland, ovaries and testicles. • Do not apply infrared light to patients who are taking drugs that have heat or light sensitive contraindications, such as but not limited to certain types of steroids.

510(k) SUMMARY continued

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Warning	• Warning: Use carefully. May cause serious burns. Do not use over sensitive skin areas or in the presence of poor circulation. The unattended use of LiteCure LCT-1000 device by children or incapacitated persons may be dangerous. • NEVER look directly into the distal end of the optical fiber connected to an active laser device, direct the laser light directly into the eyes, or direct the laser beam at anything other than the area to be treated WITH or WITHOUT the appropriate laser-emission protective eyewear. Indirect or direct eye contact with the output beam or at scattered laser light from any reflective surfaces from the laser will cause serious damage, irreparable corneal and/or retinal damage, and possible blindness to one or both eyes. • DO NOT allow any reflective object to fall into or obstruct the path of the laser energy produced by this device. Scattered or reflected laser energy can cause serious damage to eyes. The operator, all assistants, and the patient must remove all reflective objects (such as rings, metal watchbands, and jewelry) prior to treatment with this device. Indirect or direct eye contact with the output beam or at scattered laser light from any reflective surfaces from the laser will cause serious damage, irreparable corneal and/or retinal damage, and possible blindness to one or both eyes. • DO NOT remove protective eyewear until the operator returns the laser device to Standby mode. • DO NOT use the System Controls or performance of procedures other than those specified in this manual may result in hazardous radiation exposure. • DO NOT attempt to gain access to any internal device component. THERE ARE NO USER-SERVICEABLE COMPONENTS inside this laser device. Doing so may cause serious and/or irreversible injury. • AVOID THE USE of flammable solvents, anesthetics, oxidizing gases such as nitrous oxide (N_2O) and oxygen or endogenous gases. The high temperatures produced in normal use of the laser equipment may ignite some material, for example cotton or wool, when saturated with oxygen. The solvents of adhesives and flammable solutions used for cleaning and disinfecting should be allowed to evaporate before the laser equipment is used. • FAILURE TO COMPLY with all safety instructions and warnings may expose all participants to harmful levels of laser radiation and/or dangerous levels of electrical current.

510(k) SUMMARY continued

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Cautions:	• Never allow untrained personnel to operate this advice unless directly supervised by a properly trained and experienced individual • The protective eyewear supplied with this device has an optical density rating >5 in the 350nm~2000nm (see specification sheet) region. All personnel present during device operation must ware this eyewear. Contact LiteCure, LLC. at 302-709-0408 to purchase additional sets of protective eyewear for this device. • Select a secure, properly equipped, and well-ventilated location in which to install and operate the laser. • Place "Laser in use" signs at location entrances where people will use the LiteCure, LLC. laser device. • Always put the laser in Standby mode or switch the device off prior to adjusting or preparing the wand or fiber optic. • Never leave this device in the READY mode unattended. See the STANDBY to READY Mode in the Operations section of this manual. • Remove the key from the device's key switch when not in use to prevent unauthorized and/or unqualified use of the device as well as inadvertent laser emissions. • Turn the device off before relocating equipment in the same vicinity. • Never press the foot switch without first verifying the safe orientation and proper positioning of the wand and distal end of the optical fiber and ensuring compliance to all safety precautions. • During any laser procedure, do not allow any nonessential personnel into the treatment area. • Never allow the untrained personnel to operate this device unless directly supervised by a properly trained and experienced individual. • ALWAYS clean the SMA fiber tip before inserting into the SMA emission port. A dirty tip could result in damage to the unit. • Federal law (USA) restricts this device to sale by or on the order of a physician.
Substantial Equivalency Information	According to non-clinical testing, the Litecure LCT 1000 system has the same intended uses, functional and performance characteristics as the predicate devices listed. The testing demonstrated compliance to the generally accepted therapeutic heat performance specifications by producing a level of tissue temperature reported in literature and accepted by the Food and Drug Administration. The identified differences were determined to be minor and do not raise any concerns regarding the overall safety and effectiveness of the device.
Technological Characteristics	The device is subject to the following voluntary consensus standards: 21 C.F.R. § 1040.10 & 1040.11; IEC 60601-1; IEC 60601-1-2; IEC 60601-1-4; IEC 60601-2-22; IEC 61000-3-2; IEC 61000-3-3; and IEC 60825-1.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Litecure, LLC
% Intertek Testing Services
Mr. Neil E. Devine, Jr.
2307 East Aurora Road
Unit B7
Twinsburg, Ohio 44087

FEB 2 8 2007

Re: K070400
Trade/Device Name: LC Therapy, Model LCT-1000
Regulation Number: 21 CFR 890.5500
Regulation Name: Infrared lamp
Regulatory Class: II
Product Code: ILY
Dated: February 9, 2007
Received: February 12, 2007

Dear Mr. Devine:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

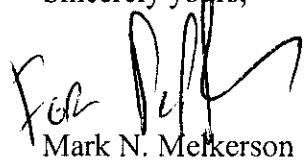
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indication For Use

510(k) Number (if known): _____

Device Name: LC Therapy, Model LCT-1000

Indications For Use:

LC Therapy, Model LCT-1000 is indicated for emitting energy in the infrared Spectrum to provide topical heating for the purpose of elevating tissue temperature for temporary relief of minor muscle and joint pain, muscle spasm, pain and stiffness associated with arthritis and promoting relaxation of the muscle tissue and to temporarily increase local blood circulation.

Prescription Use ____X____ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K070400